K121190

Bayer HealthCare

510(k) Summary

JUL 26 2012

Date prepared: July 24, 2012

According to the requirements of 21 CFR 807.92, the following information is being submitted in sufficient detail to provide an understanding of the basis for a determination of substantial equivalence.

1) Submitter	Charles Ryan Senior Manager, Regulatory Affairs Bayer Healthcare LLC 555 White Plains Road Tarrytown, New York 10951 Telephone: (914) 333-6122
2) Device name:	Trade name: CONTOUR®NEXT Blood Glucose Monitoring System FDA Product Code: NBW Classification name: Blood Glucose Test System, Over-the-Counter (21 CFR § 862.1345)
3) Predicate device:	CONTOUR®NEXT LINK Wireless Blood Glucose Meter (Reference: CONTOUR®NEXT LINK Wireless Blood Glucose Monitoring System (K110894))
4) Device description:	The CONTOUR®NEXT Blood Glucose Monitoring System consists of a small handheld blood glucose meter that utilizes dry reagent test strips and liquid controls for the measurement of glucose in capillary whole blood by persons with diabetes. The meter together with the test strips and control solutions is referred to as the CONTOUR®NEXT Blood Glucose Monitoring System.
5) Intended Use:	The CONTOUR®NEXT Blood Glucose Monitoring System is an over the counter (OTC) device utilized by persons with diabetes in home settings for the measurement of glucose in whole blood, and is for single-patient use only and should not be shared. The CONTOUR®NEXT Blood Glucose Monitoring System is indicated for use with fresh capillary whole blood samples drawn from the fingertip and palm only.

CONTOUR®NEXT Test Strips are intended for self-testing by persons with diabetes for the quantitative measurement of glucose in whole blood samples from 20 to 600 mg/dL.

The CONTOUR®NEXT Control Solutions are aqueous glucose solutions intended for use in self-testing by people with diabetes as a quality control check.

The CONTOUR®NEXT Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

Data demonstrating substantial equivalence

The CONTOUR®NEXT Blood Glucose Monitoring System features a small handheld blood glucose meter that is substantially equivalent in its intended use and fundamental scientific technology to the predicate, CONTOUR®NEXT LINK Wireless Blood Glucose Meter featured with the CONTOUR®NEXT LINK Wireless Blood Glucose Monitoring System (K110894). Both devices utilize the same CONTOUR®NEXT dry reagent strips and liquid controls for the measurement of glucose in capillary whole blood by persons with diabetes. Additionally, both devices utilize the same blood glucose measurement algorithm and automatic calibration. The chief differences between the devices is the removal of the ability to wirelessly transmit glucose results to an associated Medtronic device, the use of replaceable batteries as a power supply, and a different look and size for the meter.

The risk analysis methods used to assess the design of the subject device were a Hazard Analysis and Failure Modes and Effects Analyses (FMEA).

In brief summary, the risks identified as applicable to the CONTOUR®NEXT Blood Glucose Monitoring System are listed in the table below along with their corresponding Verification and Validation Activities' acceptance criteria and results.

Risk	Acceptance Criteria	Results
User injury from electric shock	• The meter shall not allow a test to initiate when the meter is connected to an external device (e.g. computer). • The meter shall not experience permanent damage or present hazard such as excessive temperature or heat due to overvoltage.	**Pass** • All blood glucose tests attempted while connected to PC generated "Do not Test, Connected" error screen. • All results maintained correct voltage regulation within limits and did not present temperature hazard near or above the

Risk	Acceptance Criteria	Results
	• Must meet requirements set forth in IEC 61010-1:2001 (2nd Edition)	specified limit. • Compliance with IEC 61010-1:2001 requirements confirmed via testing by an external lab.
Biocontamination – exposure to blood-borne pathogens via device	• One set of meters were soiled with CONTOUR®NEXT liquid control and another set of meters were soiled with 5 uL of venous blood. All meters were allowed to dry for 24hrs. The soil locations were the meter button and display. All meters were then cleaned with Clorox germicidal wipes. No residual blood or control solution was to be observed on any of the meters. • Test meters received contact with an EPA-approved surrogate for a human virus for 24 hours on various test surfaces. All instruments must be cleaned with wipes containing 0.55% sodium hypochlorite and no virus must be detected on any surface after 60s.	**Pass** • There was no residual blood or control solution observed on any of the meters. • The specified disinfectant passed the virus elimination effectiveness test for all tested meter device surfaces.
Material degradation due to cleaning and disinfection	Interior meter case parts and exterior meter case parts were exposed to several different cleaning agents (such as bleach solutions, isopropyl alcohol, and soap and water) that might be applied by a user. The plastic parts were not to exhibit any cracking, glazing, discoloration or expansion after being exposed. The metallic parts were to exhibit little or no corrosion and were to be evaluated based on a low, medium or high corrosion level.	**Pass** • All results for plastic and metallic parts met the specified criteria for each solution tested.
Choking/toxicity dangers from small parts (batteries)	• Reagent insert shall warn users of accidental swallowing of test strip. • User Guide shall warn users of accidental swallowing of assembly components (such as batteries, battery cover etc. • Assembly components (such as	**Pass** • Test strip insert already warns against swallowing test strips • System User Guide warns: "Keep out of reach of children. This kit contains small parts which could cause suffocation if accidentally swallowed." and

Risk	Acceptance Criteria	Results
	screws) are not required to be unscrewed for any reason. Design will utilize a non-ordinary screw and require uncommon tools to remove.	"Keep batteries away from children. Lithium batteries are poisonous. If swallowed, immediately contact your poison control center." • Device designed so that no hazardous assembly parts are easily accessible to user.
Meter malfunction – incorrect reading or does not function properly	The accuracy of the test strip driving voltage of the Analog Front End at operating temperature range shall be assessed under various test temperatures. The CONTOUR®NEXT meter data port shall withstand multiple cycles (insertions/removals). When preparing to perform a blood glucose measurement, the meter shall perform an electronics self test to verify proper function of the meter electronics.	**Pass** • All results for each test temperature were within the required mV range set forth in the testing. • All results for the meter data port were within the specified limits after multiple test strip insertion/removal cycles. • All software test conditions in validation testing passed acceptance criteria
Erroneous data transfer from meter to PC	The CONTOUR®NEXT meter's computer interface shall detect and correct communication errors, reducing the chance of data errors over the interface.	**Pass** • All software test conditions in validation testing passed acceptance criteria
User unable to properly use meter or follow its instructions for use	Product labeling for proper instrument operation shall be validated through customer focus study (summative usability study) for 2 critical tasks: 1) completing initial setup and 2) running a mock blood glucose test and marking the result using the meter and instructions for use.	**Pass** • Completing initial setup task was successful. Study subjects successfully completed a mock blood glucose test and marked the reading.
User misinterprets meter readings	Product labeling for proper instrument operation shall be validated through customer focus study (summative usability study) for 2 critical tasks: 1) completing initial setup and 2) running a mock blood glucose test and marking the result using the meter and instructions for use.	**Pass** • Completing initial setup task was successful. Study subjects successfully completed a mock blood glucose test and marked the reading.
User mishandles meter (i.e., drops meter, spills liquid on meter)	Meter must be designed to withstand drop and show no signs of damage to any components. Meter must also be designed to	**Pass** • All results withstood the stated Drop test and Spill challenges.

Risk	Acceptance Criteria	Results
	withstand Spill Test after exposure to various test solutions.	

Conclusion

The CONTOUR®NEXT Blood Glucose Monitoring System is substantially equivalent in its intended use, performance, safety and effectiveness to the predicate CONTOUR®NEXT LINK Wireless Blood Glucose Monitoring System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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Silver Spring, MD 20993

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555 White Plains Road
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JUL 26 2012

Re: K121190
Trade Name: CONTOUR NEXT Blood Glucose Monitoring System
Regulation Number: 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: NBW, LFR, JJX
Dated: June 28, 2012
Received: June 29, 2012

Dear Charles Ryan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: CONTOUR® NEXT Blood Glucose Monitoring System

Indications for Use:

The CONTOUR®NEXT Blood Glucose Monitoring System is an over the counter (OTC) device utilized by persons with diabetes in home settings for the measurement of glucose in whole blood, and is for single-patient use only and should not be shared. The CONTOUR®NEXT Blood Glucose Monitoring System is indicated for use with fresh capillary whole blood samples drawn from the fingertip and palm only.

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Prescription Use __X__ (21 CFR Part 801 Subpart D)	And/Or	Over the Counter Use __X__ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k121190